UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Offic
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Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/110,720	07/07/98	BILLING-MEDEL P	6130.US.P1

023492
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DEPT. 377 - AP6D-2
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HM22/0130

EXAMINER	
ZITOMER,S	
ART UNIT	**PAPER NUMBER**
1655	20

DATE MAILED: 01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/110,720	BILLING-MEDEL et al.
Examiner	**Group Art Unit**
Stephanie Zitomer	1655

☒ Responsive to communication(s) filed on *Nov 7, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-32, 34-44, and 49* is/are pending in the application.

Of the above, claim(s) *1-10, 15-32, 34-37, and 40-44* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *11-14, 38, 39, and 49* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Application status

1. Receipt of the amendment with attached exhibits filed November 7, 2000 is acknowledged.

2. Applicant's request is granted to hold in abeyance the compliance with the objections to the disclosure set forth at paragraph 3 of the previous Office action, paper no. 16, mailed June 9, 2000.

3. Rejections set forth in the previous Office action and not reiterated herein have been withdrawn in view of the amendments to the claims. Applicant's arguments and comments have been fully considered.

Informalities

4. The disclosure is objected to because of the following informalities:

(a) Figures 3A and 3B described at page 11 are not in the application and it is not clear that they have been filed.

(b) The use of "SEQUENCE ID NO" as a sequence designator in the specification and claims instead of "SEQ ID NO:" is improper and the disclosure thus is not in compliance with 37 CFR 1.821(d).

Appropriate correction is required.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejection under 35 U.S.C. 101: Lack of utility

5. Claims 11-14, 38, 39 and 49 are rejected under 35 U.S.C. 101 because the claimed nucleic acids are not supported by either a specific and substantial asserted utility or a well established utility. The specification describes the claimed invention at page 23 as "reagents such as polynucleotide sequences derived from a breast tissue of interest and designated BS200". It is stated at least at pages 64 and 65 that assays indicating the presence of BS200 "suggest[ing] a diagnosis of a breast tissue disease or condition, such as cancer". However, at page 57 it is indicated that in a database search the "consensus sequence" (SEQ ID NO:16) was found in only about 39% of breast tissue libraries versus 5% in non-breast tissue libraries, i.e. about 7 times more often in breast than non-breast

tissue. With regard to the occurrence of BS200 in diseased or malignant breast tissue, it is reported at page 68 that PCR products of BS200 were seen in both normal breast and breast cancer tissue, illustrated in Figures 3A and 3B which are not in the application. Therefore, the claimed BS200 nucleic acids do not even have tissue specificity and can be used only to detect BS200 which has not been shown to have any biological significance, i.e., they do not have specific *or* substantial utility. Absent information on the role of the BS200 consensus sequence or the function of the putative protein it encodes the claimed nucleic acids cannot have any "real world" utility.

Rejection under 35 U.S.C. 112, first paragraph: Lack of enablement based on lack of utility

6. Claims 11-14, 38, 39 and 49 are also rejected under 35 U.S.C. 112, first paragraph, as being nonenabled. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above in paragraph 3, one skilled in the art clearly would not know how to use the claimed invention.

Response to applicant's arguments.

7. Applicant's arguments filed November 7, 2000 have been fully considered but they are not persuasive. Basis for the argument that "BS200 is approximately 7 times more abundant in breast tissue than in the rest of the body" (emphasis added) is unclear as the cited "data obtained from the Lifeseq database developed by Incyte Pharmaceuticals" is not in the disclosure and the specification does not indicate which body compartment libraries represent "the rest of the body". (It is noted that analysis of RNA extracted from normal and cancer lung and colon tissues for BS200 RNA was negative (page 68, lines 10-13).) It is further unclear how the appearance of CEA in serum which is an indicator of colon cancer stage (Hammarstrom, page 76, column 2, first full paragraph) relates to "the appearance of BS200 protein or mRNA in a patient blood sample" which, in any case, is not taught in the specification. The assay of RNA extracted from PMBCs (pages 61-62 at B.; also see blotting Examples 5 and 6) is wholly unrelated to the measurement of nucleic acids in serum; no results are given for the assay. The comparison of BS200 with EGF is interesting but like the comparison with CEA it is remote from the subject matter of the claimed invention. The statement that some proteins having EGF-like domains are involved

in cancer is unsupported. The cited abstract (Exhibit B) does not mention cancer but summarizes a review of structure-function studies to identify amino acids involved in binding specificity. It is argued further that "under the Revised Interim Utility Guidelines [reference to Fed. Reg. 61(244) of Dec. 21, 1999 is assumed] which specifically states that utility is acceptable if it is "believable to a person of ordinary skill in the art based on the totality of the evidence and reasoning provided". This argument is based on a misrepresentation of the Guidelines in that the requirement that the asserted utility be a "specific and substantial" utility has been omitted. Therefore, the assertion that "the threshold to be met by Applicant is a **credible assertion** of utility" (original emphasis) is specious and untenable. Furthermore, the claim that "BS200's use in diagnostic test in order to determine whether a patient has a disease of the breast unquestionably illustrates a credible utility" is a conclusory statement lacking support anywhere in the disclosure. Lawyers' arguments unsupported by factual evidence are...mere conclusory statements...and...are entitled to little weight when Patent Office questions efficacy of statements. Quote from *In re Lindner*, 173 USPQ 356 (CCPA 1972).

Rejection under 35 U.S.C. 112, first paragraph: Lack of written description

8. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim encompasses a large genus of polynucleotide species which are undescribed. The specification discloses the claimed nucleotide sequences, SEQ ID NOS:1-3, 6, 9 and 14-16 as well as the amino acid sequences, SEQ ID NOS:31-35. However, the polynucleotide of claim 14 which comprises "a sequence encoding at least one BS200 epitope" represents a large genus of species of polynucleotide sequences encoding epitopes not one of which is disclosed in the specification. Furthermore, the specification fails to teach how to make a representative number of the polynucleotide species encompassed by the claims. The polynucleotide genus encompasses sequences of an indeterminate number of nucleotides encoding epitopes of undisclosed sequence and size. Although the specification describes construction of a fusion protein and the generation of antibodies employing the fusion

protein as well as unconjugated peptides, SEQ ID NOS:32-35, (pages 80-84) not analysis of the antibody binding portions of the peptides is described. In addition to enablement the first paragraph of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. Absent written description of a representative number of the claimed polynucleotide encoding at least one BS200 epitope the specification does not demonstrate that applicant was in possession of the claimed invention at the time the application was filed.

Applicant's response

9. The previous arguments's are cited in response to this rejection. However, those arguments do not address the lack of written description issue.

Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

10. Claims 11-14, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 11 is are confusing in the redundant use of "polynucleotide". It is suggested to change the third "polynucleotide" in claim 11 to --nucleotide sequence--.

(b) Claims 11 lacks proper antecedent basis in "polynucleotide" for the sequences represented by their SEQ ID NOS:. It is suggested to change the third "polynucleotide" in claim 11 to --nucleotide sequence--. (Same as above.)

(c) Claim 38 lacks proper antecedent basis for "the amino acid sequence". It is suggested to change "the" to --an--.

(d) Claims 39 is confusing because it is unclear how SEQ ID NO: (*sic* SEQUENCE ID NO) 15 and 16 are to be combined or if they are to be combined for determining the "DNA having at least 50% identity" therewith. It is suggested to change "and" to --or-- or to clarify otherwise.

Applicant's response

11. Contrary to the statement that "Applicant has complied with the Examiner's suggestion" no amendments to the claims address the issues raised under 112, second paragraph.

Conclusion

12. **No claim is allowed.**

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

S. Zitomer
Stephanie Zitomer, Ph.D.
January 26, 2001